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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,306	09/25/2006	David Becker	US040173US	1780

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EXAMINER

GUPTA, VANI

ART UNIT	PAPER NUMBER
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3768

MAIL DATE	DELIVERY MODE
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,306	Applicant(s) BECKER ET AL.	
	Examiner VANI GUPTA	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 12, 2010 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. *Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Silverstein et al. (US 5,178,150).*

Regarding Claim 1, Silverstein et al. discloses an ultrasonic intracavity probe (*endoscope, fig. 1, 30*) for scanning a volumetric region from within the body comprising: a handle section to be held during the use of the probe (*fig. 1, 36; col. 4, ll. 58 – 60*); a shaft section having a distal end (*12*), which is to be inserted into a body cavity during use of the probe (*fig. 1, 32*); and a transducer disposed at the distal end, wherein an array ultrasound transducer (*fig. 1, 52*), capable of producing two-dimensional images (*col. 4, ll. 61 – 66*).

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Silverstein also discloses that the transducer is pivotally movably mounted (*“rotationally,” “linearly,” etc. – col. 4, ll. 55 – 58*) within the fluid chamber/balloon (***flexible bag, 62***). ***Figures 2 - 4*** depict an arrangement of the transducer within the fluid-chamber-balloon combination. The liquid bath (or acoustic coupling fluid (***64***)) is within the fluid-chamber/flexible-bag located at the distal end of the shaft (*col. 3, lines 14- 16*) and therefore, is constrained to the shaft section to the exclusion of the handle section. According to ***figs. 2 - 4***, a portion of the coupling fluid is located between the array transducer and the distal end of the shaft during scanning.

The pivotally mounted array transducer (52) is located also in a rigidly dimensioned compartment at the distal end of the shaft section (fig. 4, #50 and 70), wherein the transducer body (50) and curved portion (70) make up the rigidly dimensioned compartment. As shown in fig. 4, the compartment is located at the distal end.

Additionally, since the acoustic coupling fluid (64) is contained within the area of the compartment, and in fact surrounds the compartment, the fluid is also within the compartment.

A motor is located in the handle section (*col. 6, line 59 – col. 7, line 13*) and is connected or coupled to the array transducer by a drive mechanism (*“actuating rod,” col. 6, line 35 – 58*) that move the array transducer during scanning (*col. 6, line 35 - col. 7, line 38*).

With respect to the “center of gravity of the probe” being located in the handle section – since the distal end comprises a “hallow” distal actuating rod (col. 5, ll. 49 - 54), and the distal end is proportionally smaller (see figures) so that is can be inserted into a cavity of a patient; and the proximal end of the probe comprises a proportionally larger handle comprising several gears and other parts (*col. 6, line 59 – col. 7, line 13*) – it is clear that the handle portion of the probe

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would be heavier. Therefore, the center of gravity would reside at the handle portion of the probe.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Inventorship

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 4 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverstein et al. (US 5,178,150) as applied to claims 1 and 2 above, and further in view of Larson et al. (US 6,039,694).

Regarding claims 4 – 10, Silverstein et al. discloses an ultrasonic intracavity probe comprising transducer mount assembly located in the distal end of the shaft of the probe and a liquid bath located within the transducer assembly.

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Silverstein et al. does not disclose specifically that the transducer mount assembly has a proximal termination within one and one-half of the distal end of the shaft section. Silverstein et al. also does not disclose specifically that 90% of the liquid bath is contained within the transducer mount assembly; or that liquid bath has a volume of “less than 25 cc of liquid,” or “less than 10 cc of liquid,” or “approximately 6 cc of liquid;” or that 90% of the liquid bath in the most distal 25% of the length of the shaft section.

Nonetheless, Larson et al. teaches a coupling sheath for ultrasound transducer that is conformal and performs as if integral to the transducer mount assembly. Furthermore, the coupling sheath comprises preferably about 70 to 95% biocompatible liquid (*Abstract*). Larson et al. also teaches a homogenous, solid, elastic, biocompatible sheath comprising biocompatible fluid that renders properties to the sheath, resulting in desirable levels of acoustic coupling (*Abstract*).

Therefore, it would be prima facie obvious to modify the coupling fluid of Silverstein et al. with the coupling sheath of Larson et al. to obtain an ultrasound intracavity probe that leaves no harmful residue when used with the body orifices and remains lubricous when in contact with bodily fluids (*Abstract*).

Furthermore, it would be prima facie obvious to modify Silverstein et al. with Larson et al. to dispose the coupling sheath within one and one-half inches of the terminus of the distal end of the probe for optimal results with coupling of the distal end for “providing optimal delivery of ultrasound within the cavity of a patient,” and for “good coupling from the transducer through the impedance matching fluid to the [intracavity of the patient],” as required by Silverstein et al. (*col. 5, ll. 45 – 48; col. 5, line 66 – col. 7, line 2*).

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3. *Claims 11 – 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverstein et al. (US 5,178,150) as applied to Claim 1 above, further in view of Bushek et al. (US 6,315,710).*

Regarding claims 11 – 16, Silverstein et al. discloses a transducer mount assembly, wherein the transducer array (52) is mounted to a transducer mount assembly having a main body and located in the distal end of the shaft section, which extends from the handle such that the transducer array is free to rotate or pivot about the axis of transducer region (*figs. 2 and 4, 50, 54, 58, 80; col. 6, ll. 35 – 58*).

Silverstein et al. does not disclose specifically that the main body of the transducer mount assembly is formed of material lighter than stainless steel.

However, Bushek et al. teaches a hearing device, insertable into a cavity such as a ear, comprising a transducer mount assembly (*fig. 11, 220*) formed from a material other than stainless steel such as polycarbonate, silicone, titanium, etc. (*col. 13, lines 60 – 67*). Bushek et al. also teaches a mount assembly that the rotation and delicate positioning of the transducer (*col. 13, lines 52 – 59*).

Applicant should note that although Bushek et al. teaches that the transducer can be secured by additional means such as a screw, this does not teach away from the feature that the transducer mount assembly still allows the rotation of transducer.

Therefore, it would be prima facie obvious to combine Silverstein et al. with Bushek et al. to obtain a transducer mount assembly made of materials lighter than stainless steel for rotability of the transducer.

With further respect to Claim 12, Silverstein et al. suggests in **Fig. 4** that transducer mount assembly portion (50) provides a transducer cradle, which supports transducer array (52).

With further respect to claims 13 and 14, transducer cradle includes a solid body (70) located behind array transducer which displaces volume of coupling fluid; it is shaped so that it passes more easily through the liquid bath (**Fig. 4**).

With further respect to claims 15 and 16, Silverstein et al. teaches that the transducer mount assembly includes wear surfaces (**Fig. 4, #80, 120, 122**), wherein wear surfaces are part of the drive mechanism (*col. 6, ll. 40 – 45; and col. 7, ll. 22 – 25*); and teaches that the transducer mount assembly may be formed of materials such as stainless steel (*col. 7, ll. 3 and 20*).

4. *Claims 17 – 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverstein et al. (US 5,178,150) as applied to Claim 1 above, further in view of Bushek et al. (US 6,315,710) as applied to Claim 11, and in further view of Fukumoto et al. (US 6,621,065 B1).*

Regarding Claim 17 – 20, Silverstein et al. teaches an intracavity probe comprising a transducer mount assembly.

Silverstein et al. in further view of Bushek et al., teaches that components of the transducer mount assembly may be made of materials lighter than stainless steel.

However, Silverstein et al., in further view of Bushek et al., does not teach that that the weight is less than 400 grams, or less than 300 grams, or approximately 250 grams; or that shaft of the intracavity probe is made with materials at least equal to the density of the stainless steel components of the drive mechanism for optimal results with respect to localizing the center of gravity in the handle section of the probe

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Nevertheless, Fukumoto et al. teaches an imaging probe may comprise a mass of 500 grams or less (hence less than 400 grams) (*col. 7, lines 22 - 26*). Fukumoto et al. also teaches that the probe may be made of a material such as magnesium alloy, which allows the light mass of the probe.

Furthermore, as is known in the art, magnesium alloy comprises a density that is less than the density of stainless steel.

Accordingly, Fukumoto et al. teaches that magnesium alloy is malleable in that it can be thinned for scalability purposes and has a property for shielding electromagnetic waves (*col. 5, lines 54 – 55*). As is known in the art, electromagnetic waves may commonly occur in medical imaging settings. Additionally, as would be obvious to one of ordinary skill in the art, Fukumoto et al.'s imaging probe may be scaled so that it can fit with a natural cavity of a patient. As discussed above, magnesium alloy's scalability allows as much.

Therefore it would be *prima facie* obvious to combine Silverstein et al., in further view of Bushek et al., with Fukumoto et al. to obtain an imaging probe that can be made of magnesium alloy for less mass and scalability purposes.

Response to Arguments

Applicant's arguments filed January 12, 2010 have been fully considered but they are not persuasive.

Applicant argues on page 6 of Remarks/Arguments that Silverstein et al. cannot anticipate Claim 1 because Silverstein et al. teaches a two-dimensional imaging probe while present Claim 1 allegedly claims a volumetric imaging probe. However, Applicant should note

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that this feature that feature that Applicant refers to is in the preamble of the claim and not the body of the claim. Therefore, it has not been given patentable weight. Applicant also should note that a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In this case, the structure claimed within the body of the claim does not depend on whether the transducer is two-dimensional-imaging capable or three-dimensional-imaging capable. It only requires that that imaging transducer comprises an array, which Silverstein et al. teaches.

Applicant also argues on page 6 that Silverstein et al. does not provide a pivotally mounted array transducer as claimed in Claim 1, but a single piston transducer. Examiner respectfully disagrees and directs Applicant to column 3, line 66 – column 4, line 2, where Silverstein et al. teaches that the transducer body may rotate or reciprocate – in other words, pivot.

Applicant also argues that the compliant bag (62) of Silverstein et al. does not comprise a “rigidly dimensioned compartment,” and therefore Silverstein et al. does not teach this feature of Claim 1. Examiner respectfully disagrees and points out that the distal end comprises components besides the compliant bag that make up the rigidly dimensioned compartment. Please see figs. 2 and 4, and the above rejection for more details.

Applicant also argues that the components of Silverstein et al. (stainless steel rod, 54,82, 86; and triple helix wound spring, 56) make up most of most of the length of the probe, and

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therefore, the center of gravity of probe is in the center of the probe and not at the handle, as claimed in Claim 1. Examiner respectfully disagrees. If anything, this portion of the probe would be lighter than the handle portion because it would be nearest the insertion portion that is inserted in to the cavity of the patient, and one would want these components to be light for greater comfort and safety to the patient. By the same token, the components near the handle section would be bigger to hold the actuating member which in it and of itself would be heavy (fig. 4, #90). Additionally, by the looks of fig. 1, the handle portion is bigger than the distal end. There is nothing to suggest that the compliant bag (62) is so bulky, that it is bulkier than the handle portion (as Applicant argues on page 5). There is also nothing to suggest that the acoustic fluid (64) contained with the bag makes the distal end heavier than the handle portion. Such is a mere conjecture on the Applicant's part. There is also nothing to suggest that the compliant bag could rupture, tear, or "break," as argued by the Applicant on page. This matter is irrelevant anyhow, since this feature is not being claimed.

Applicant also argues that secondary reference Larson et al. does not teach the features of claims 4 – 10. Examiner respectfully disagrees. Silverstein et al. provides the liquid compliant bath or compartment, and Silverstein et al. in view of Larson et al. teaches the other claimed features of the present claims 4 – 10 (in Abstract). Please see above rejections for further details.

Applicant also argues that Bushek et al. does not remedy the deficiencies of Silverstein et al. and is not relevant prior art. Examiner respectfully disagrees and directs Applicant to above rejection and responses to arguments. As indicated above, Bushek et al. teaches useable materials other than stainless steel for components that must fit within a small intrabody cavity. Applicant has not claimed that the intracavity probe of the present invention is for a specific intracavity of a

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patient's body, nor has Applicant indicated any unsolved problem or unexpected results by using Bushek et al. Additionally, in a simple mechanical invention a broad spectrum of prior art must be explored and it is reasonable to permit inquiry into other areas where one of ordinary skill in the art would be aware that similar problems exist. See *In re Bigio*, 381 F.3d 1320, 1325-26, 72 USPQ2d 1209, 1211-12 (Fed. Cir. 2004).

Applicant's arguments with respect to claims 17 – 20 are moot in light of above arguments and rejections.

Applicant's arguments with respect to claims 1 and 2 have been addressed above.

In conclusion, present claims 1, 2, and 4 – 20 are still rejected and are not in condition for allowance.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANI GUPTA whose telephone number is (571)270-5042. The examiner can normally be reached on Monday - Thursday (8:30 am - 6:00 pm; EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. G./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768